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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/444,284	11/19/1999	RONALD VOGELS	4231US	8464
7590	11/20/2003		EXAMINER	
ALLEN C TURNER TRASK BRITT & ROSSA P O BOX 2550 SALT LAKE CITY, UT 84110			CHEN, SHIN LIN	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/444,284	VOGELS ET AL.	
	<b>Examiner</b> Shin-Lin Chen	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 02 September 2003.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 2,21,25,28-32,37,44,50,51,54,56-62,64,65 and 69-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 28-32 is/are allowed.
- 6) Claim(s) 2,21,25,37,44,50,51,54,56-62,64,65 and 69-71 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

## **DETAILED ACTION**

Applicants' amendment and declaration under 37 CFR 1.801 to 1.809 filed 9-2-03 have been entered. Claims 2, 21, 25, 37, 44, 50, 51, 56, 58, 60, 61 and 69 have been amended. Claims 19, 38-40, 42, 45-49, 52, 53, 55, 63 and 66-68 have been canceled. Claims 2, 21, 25, 28-32, 37, 44, 50, 51, 54, 56-62, 64, 65 and 69-71 are pending and under consideration.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 2, 21, 25, 37, 44, 50, 51, 54, 56-62, 64, 65 and 69-71 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for adenovirus fiber 16 chimera that infects HUVEC endothelial cells or smooth muscle cells significantly better than the control adenovirus type 5 *in vitro* and none of the disclosed fiber chimeras are targeted specifically to liver and spleen *in vivo*, does not reasonably provide enablement for recombinant adenovirus 12, 16, 28, or 40-L comprising any tissue determining fragment with a reduced tropism for liver cells, an adenovirus capsid with a reduced tissue tropism for liver cells comprising proteins from at least two different adenoviruses and at least one protein includes at least a tissue tropism determining fragment of a fiber protein of adenovirus 12, 16, 28, or 40-L, a method of making said adenovirus capsid, a recombinant adenovirus comprising a recombinant adenovirus capsid having peptides from at least two different adenoviruses and at least one of said peptides comprises a tissue tropism determining fragment of a fiber protein of adenovirus

11, 16, 35, or 51, and said recombinant virus capsid has an increased tropism for endothelial cells when compared to wild type adenovirus capsids, a composition comprising the recombinant adenovirus of claim 2, and any recombinant adenovirus having a capsid with a reduced tropism for liver cells or an increased tropism for smooth muscle cells and endothelial cells, wherein said recombinant adenovirus comprises a chimeric fiber protein comprising at least the knob domain of a fiber protein of adenovirus type 11, 16, 35, or 51 and the remaining part of the fiber protein is of a different adenovirus serotype. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims and is repeated for the reasons set forth in the preceding Official action mailed 6-6-03 (Paper No. 27). Applicant's arguments filed 9-2-03 have been fully considered but they are not persuasive.

Applicants argue that the claims have been amended to read on the tissue tropism determining fragment of adenovirus 12, 16, 28, or 40-L or adenovirus 11, 16, 35, or 51 and the specification discloses recombinant adenovirus or capsids having an increased tissue tropism for endothelial cells or smooth muscle cells and method of reducing a tissue tropism of a recombinant adenovirus using peptides of a fiber protein (amendment, p. 14, 15). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 6-6-03 (Paper No. 27). Although the claims have been amended to specify the recited adenoviruses, the claims encompass using various protein fragments of fiber proteins from different adenoviruses to reduce tissue tropism for liver cells or to increase tissue tropism for endothelial cells and smooth muscle cells. The specification fails to disclose the structural feature of various adenovirus fiber proteins that contributes to the reduced tropism for liver cells or increased

tropism for endothelial cells and smooth muscle cells. Since protein function was unpredictable from mere amino acid sequence, one skilled in the art at the time of the invention would not know whether the claimed recombinant adenoviruses or recombinant adenovirus capsids would have a reduce tropism for liver cells or an increased tropism for cndothelial cells and smooth muscle cells and would not know how to use the claimed recombinant adenoviruses or adenovirus capsids. Thus, one skilled in the art at the time of the invention would require undue experimentation to practice over the full scope of the invention claimed.

***Conclusion***

Claims 2, 21, 25, 37, 44, 50, 51, 54, 56-62, 64, 65 and 69-71 are rejected. Claims 28-32 are in condition for allowance.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.



Shin-Lin Chen, Ph.D.